JUL 25 2007

Section 5: 510(k) Summary

The assigned 510(k) number is: K053613

Company:	Theo Manufacturing BV Bredestraat 33A Maastricht NL-6211 HB The Netherlands Telephone: 31 43 325 1773 Fax: 31 43 326 1022
Contact:	Barbara DeBiase
Date Prepared:	July 17, 2007
Proprietary Names:	L-Mesitran® Dressing Family • L-Mesitran Hydro • L-Mesitran Border • L-Mesitran Active • L-Mesitran Net
Classification Name:	Dressing
Common Name:	Wound Dressing
Classification Code:	Dressing, Product Code FRO
Predicate Device:	Southwest Technologies' Elasto-Gel Dressings, #K872165
Device Description:	L-Mesitran Hydro, L-Mesitran Border, and L-Mesitran Active are hydro-active hydrogel wound dressings containing honey. L-Mesitran Net is a hydro-active hydrogel coated wound dressing containing honey on an open weave polyester net.
Intended Use:	<u>L-Mesitran Hydro and Border</u> L-Mesitran Hydro and Border dressings are indicated for acute and chronic superficial wounds such as: bruises, cuts, bedsores, first and second-degree burns and other traumatic wounds, venous and arterial ulcera, diabetes ulcers, donor sites, and post-operative wounds. L-Mesitran Hydro and Border should not be used as a covering for deep narrow cavities, dirty wounds (these should first be cleansed), third-degree burns and fistulae. Maintains a moist wound healing environment. This moist environment supports optimal wound healing.

L-Mesitran Active
L-Mesitran® Active dressings are indicated for treating minor burns, superficial cuts, lacerations and abrasions, and other small wounds. Maintains a moist wound healing environment. This moist environment supports optimal wound healing.

L-Mesitran Net
L-Mesitran dressings are indicated for acute and chronic superficial wounds such as: bruises, tears, pressure ulcers, venous and arterial ulcera, diabetes ulcers, donor sites, cuts, first and second degree burns, postoperative wounds and other external wounds caused by trauma. L-Mesitran Net is to be used in conjunction with other secondary dressings. It should not be used on its own as a covering for dirty infected and heavily exudating wounds (should first be cleansed), third degree burns, or deep narrow cavities. Maintains a moist wound healing environment. This moist environment supports optimal wound healing.

Performance Data

Biocompatibility study and performance test results demonstrate that L-Mesitran Dressings are non-irritating, non-sensitizing and non-toxic.

Conclusion:

The L-Mesitran Dressing Family is substantially equivalent in function and intended use to Elasto-gel Dressings (#K872165).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2007

Theo Manufacturing BV
% QNet LLC
Ms. Barbara DeBiase
Project Consultant
1467 vigilante Avenue Suite 405
Bailey, Colorado 80421

Re: K053613
Trade/Device Name: L-Mesitran® Dressing Family
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 20, 2007
Received: June 21, 2007

Dear Ms. DeBiase:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

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510(k) Number (if known): K053613

Device Name: L-Mesitran® Dressing Family

Indications for Use:

L-Mesitran Hydro and L-Mesitran Border
L-Mesitran Hydro and Border dressings are indicated for acute and chronic superficial wounds such as: bruises, cuts, bedsores, first and second-degree burns and other traumatic wounds, venous and arterial ulcera, diabetes ulcers, donor sites, and post-operative wounds.

L-Mesitran Hydro and Border should not be used as a covering for deep narrow cavities, dirty wounds (these should first be cleansed), third-degree burns and fistulae.

L-Mesitran Net
L-Mesitran Net Dressings are indicated for acute and chronic superficial wounds such as: bruises, skin tears, pressure ulcers, venous and arterial ulcera, diabetes ulcers, donor sites, cuts, first and second degree burns, postoperative wounds and other external wounds caused by trauma. L-Mesitran Net is to be used in conjunction with other secondary dressings.

It should not be used on its own as a covering for dirty, infected and heavily exudating wounds (should first be cleansed), third degree burns, or deep narrow cavities.

Prescription Use ___XX____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K053613

Indications for Use

(Page 2 of 2)

510(k) Number (if known): K053613

Device Name: L-Mesitran® Dressing Family

Indications for Use:

L-Mesitran Active
L-Mesitran Active Dressings are indicated for treating minor burns, superficial cuts, lacerations and abrasions, and other small wounds.

Prescription Use _____ AND/OR Over-The-Counter Use ___XX____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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and Neurological Devices

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